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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,461	05/18/2000	Roger J. Talish	601-61	6818
30559 7590 07/27/2007 CHIEF PATENT COUNSEL SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116			EXAMINER FERNANDEZ, KATHERINE L	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 07/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/574,461

Applicant(s)

TALISH ET AL.

Examiner

Katherine L. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 6/21/07, 7/5/07; 9-11-06

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/2007 has been entered.

***Information Disclosure Statement***

The Information Disclosure Statements filed on June 16, 2007 and July 5, 2007 are acknowledged. The Information Disclosure Statements meet the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 8-15, 17-20, and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich et al. (US 5,476,438) in view of Talish (5,556,372), and further in view of Gruber (US 4,570,487).

Edrich et al. '438 teaches a method and apparatus of neuromagnetic simulation. The patent simultaneously directs a focused beam of ultrasonic waves with an applied

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magnetic field to simulate a region of interest. Fig 3 of Edrich et al. '438 depicts a schematic of the system including ultrasound transducer source (1) which focuses the ultrasound waves into a region, coils (7) that produce magnetic fields, drivers 16 and 17 for providing a driving signal to the transducer and coil, respectively. A synchronizer (18) and delay circuit (19) perform the function of frequency and phase control of the magnetic and ultrasound signals. The synchronizer (18) and delay circuit (19), and drivers (16 and 17) function as the main operating unit for driving the ultrasound transducer and magnetic coils. The patent teaches that the system can enclose the head in a helmet-like fashion thereby satisfying the applicant's limitation to a placement module configured to be worn by the patient, column 5 Lines 1-5. The coupling of driver 16 and 17 to ultrasound source and magnetic coils, respectively, as shown in figure 3 teaches the limitation to a first and second cable. The teachings to frequency and phase control of the ultrasound and magnetic waveforms encompasses the step of varying the magnitude of the waveform as taught by applicant, column 3 line 51 through column 4 Line 6. Furthermore the patent teaches that the relationship of the applied ultrasound and magnetic waves is adjusted to achieve optimum stimulation performance. To reiterate, Edrich et al. teaches the direction of the acoustic waves with respect to the magnetic wave enhanced the therapeutic procedure, in that a magnetic field with a magnetic induction (flux)  $B$  orthogonal to the focused ultrasound wave will result in enhanced or improved therapy to the region of interest, column 2. The magnetic field and the ultrasound wave are applied simultaneously, furthermore a superimposition of the two waves occurs. More specifically column 2 Lines 25-31 recites "the method of

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the invention achieves the unexpected advantage that by the superimposition of the focused ultrasound, the relatively large magnetic fields required to be effective can be directed onto a single nerve bundle..." Superimposition is defined as to lay on top. With respect to applicant's limitation of modulating the acoustic wave, the superimposition by the ultrasound of the reference means the same thing. The electromagnetic wave is laid onto to of the ultrasound wave to focus the therapy of the reference is the same thing as the ultrasound wave modulated by the electromagnetic wave. With respect to the additional limitation of "wherein either said at least one ultrasound transducer or said at least one electromagnetic coil can be selectively biased relative to the other to modulate the energy" or "selectively biasing either said at least one ultrasound transducer or said at least one electromagnetic coil relative to the other to modulate said ultrasound waves" of claims 30-31 Examiner directs attention to figure 3 and column 4 Lines 7-10 which diagram the placement of the two and disclose that the relationship of the waves should be properly adjusted for optimum stimulation performance. In light of applicant's specification Examiner interprets "selectively biasing" as placement of the two (transducer and coils) or method of application of the two waves (ultrasound and electromagnetic) such that modulation is achieved', the Edrich reference clearly satisfies the applicant's Limitation. The limitation of a conductive material that couples main operating unit to the at least one ultrasound transducer and at least one coil and the non-uniform magnetic field are inherent to the functionality of the invention. Edrich et al. teaches simultaneous application of ultrasound and magnetic waveforms to stimulate a region of interest. The patent teaches that the relationship of the two waveforms affects

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the extent of therapy that is received by the tissue. Furthermore it is taught that applying the magnetic flux orthogonal to the ultrasound waveform optimizes the therapeutic procedure. Figure 3 of Edrich et al. patent is a schematic of the system, the coils 7 appear to be orthogonal to the ultrasound transducer. The patent does not describe in angular positioning of transducer and coil with respect to each other. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide angular descriptions because figure 3 satisfies a angle  $0$  greater than or equal to zero and less than or equal to 90 degrees. The patent does not explicitly recite the coil wrapped around the placement module or the transducer placed closer to treatment area than coil. It would have been obvious to a person of ordinary skill in the art to have alternatively provided these configurations so as long as the magnetic flux is orthogonal to ultrasound wave thereby enhancing or optimizing therapy as taught by Edrich et al. '438. Edrich et al. '438 teaches a method and apparatus of neuromagnetic simulation. The patent simultaneously directs focused beam of ultrasonic waves with an applied magnetic field to simulate a region of interest. Fig 3 of Edrich et al. depict a schematic of the system including ultrasound transducer source (1) which focuses the ultrasound waves into a region, coils (7) that produce magnetic fields, drivers 16 and 17 for providing a driving signal to the transducer and coil, respectively. A synchronizer (18) and delay circuit (19) perform the function of control means to vary the applied ultrasound and magnetic waves, column 3-4. The patent teaches that the system can enclose the head in a helmet-like fashion, column 5 Lines 1-5. The teachings to adjusting the two waveforms encompass variation of the spatial distribution of the

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waves. Furthermore the patent teaches that the relationship of the applied ultrasound and magnetic waves is adjusted to achieve optimum stimulation performance. To reiterate, Edrich et al. '438 teaches the direction of the acoustic waves with respect to the magnetic wave enhanced the therapeutic procedure, in that a magnetic field with a magnetic induction (flux)  $B$  orthogonal to the focused ultrasound wave will result in enhanced or improved therapy to the region of interest, column 2. More specifically column 2 Lines 25-31 recites "the method of the invention achieves the unexpected advantage that by the superimposition of the focused ultrasound, the relatively large magnetic fields required to be effective can be directed onto a single nerve bundle..." Superimposition is defined as to lay on top. With respect to applicant's limitation of modulating the acoustic wave, the superimposition by the ultrasound of the reference means the same thing. The electromagnetic wave is laid onto to of the ultrasound wave to focus the therapy of the reference is the same thing as the ultrasound wave modulated by the electromagnetic wave. The patent does not teach the specific structural component of the therapeutic apparatus.

Talish et al. '372 teaches an ultrasound therapeutic apparatus, figures 1 and 3. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have alternatively provided the coil and transducer means as the portable configuration of Talish et al. figure 3 because it allows for patient mobility while optimizing therapy. Further it can be positioned to administer therapy to any desired region rather than the helmet like structure of Edrich et al. '438, such as adjacent to an injury or defect in bone.

However, Edrich et al. in view of Talish et al. do not specifically disclose that the electromagnetic coil is adapted to be selectively positioned in different orientations with respect to the ultrasonic transducer to vary the modulation of the ultrasound energy. Gruber discloses ultrasonic testing methods and units for characterizing planar flaws in hard-to-inspect materials such as welded and clad pipes containing intergranular stress corrosion cracks (column 2, lines 17-40). They disclose the use of a first and second transducer, with the second transducer having a different angular orientation to the examination surface than said first transducer (column 13, lines 13-25). At the time of the invention, it would have been obvious to one of ordinary skill in the art to selectively position the electromagnetic coil in different orientations with respect to the ultrasonic transducer. The motivation for doing so would be to cross-focus the energies through the target area to enhance the signal-to-background ratio, as taught by Gruber (column 8, lines 37-46).

4. Claims 7, 16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich et al. '438 in view of Talish '372 and Gruber in further view of Slayton et al. (6,050,943).

The system and method of Edrich et al. '438 in view of Talish '372 teaches simultaneous magnetic and ultrasound application for region stimulation. In addition, Edrich et al. '438 column 5 lines 5-7 disclose providing feedback via CAT, MRI, or diagnostic ultrasound scanning to monitor the therapy. Edrich et al. '438 in view of Talish '372 does not teach wherein said at least one ultrasound transducer includes means for receiving reflected diagnostic data. Slayton et al. '943 teaches a single



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ultrasound transducer that can both image and treat tissue. It would have been obvious to a person of ordinary skill in the art to have further to combine the teachings of Edrich and Slayton, thereby further receiving diagnostic ultrasound signals by said at least one ultrasound transducer because Edrich et al. '438 already discloses the advantage of providing diagnostic ultrasound to control the therapy and Slayton et al. '943 introduces providing the two (imaging and therapy) utilizing a single transducer which a well-known expedient in the art. The single transducer for both functions precludes from additional components within the apparatus and enables a more efficient therapeutic procedure as taught by Slayton et al '372.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
ELENI MANTIS MERCADER  
SUPERVISORY PATENT EXAMINER